VITAFOL-OB PLUS DHA PRENATAL SUPPLEMENT PLUS DHA- vitamin a, ascorbic acid, vitamin d, .alpha.-tocopherol, thiamine mononitrate, riboflavin, niacin, pyridoxine hydrochloride, folic acid, cyanocobalamin, calcium, iron, magnesium, zinc, copper, and doconexent
Exeltis USA, Inc

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Vitafol ®-OB+DHA

Prenatal Supplement with DHA

Rx

COMPOSITION

Each Vitafol ®-OB caplet contains:

Vitamin A (as beta carotene)	810 mcg RAE
Vitamin C (as ascorbic acid)	70 mg
Vitamin D (as cholecalciferol)	10 mcg
Vitamin E (as dl-alpha tocopheryl acetate)	13.5 mg
Thiamin (Vitamin B1 as thiamine mononitrate)	1.6 mg
Riboflavin (Vitamin B2)	1.8 mg
Niacin (as niacinamide)	18 mg NE
Vitamin B6 (as pyridoxine hydrochloride)	2.5 mg
Folate (as folic acid)	1700 mcg DFE
Vitamin B12 (as cyanocobalamin)	12 mcg
Calcium (as calcium carbonate)	100 mg
Iron (as ferrous fumarate)	65 mg
Magnesium (as magnesium oxide)	25 mg
Zinc (as zinc oxide)	25 mg
Copper (as copper oxide)	2 mg
Each DHA softgel capsule contains:	
Docosahexaenoic acid (DHA) (from natural algal oil)	250 mg

Other ingredients: gelatin (bovine), gylcerin, microcrystalline cellulose, croscarmellose sodium, silicon dioxide, maltodextrin, copovidone, stearic acid, water, hydroxypropyl methylcellulose, dicalcium phosphate, acacia gum, titanium dioxide, polydextrose, starch, magnesium stearate, triacetin, modified food starch, mannitol, vitamin E alcohol, polyethylene glycol, talc, FD&C Blue #1, FD&C Blue #2. **Contains: Soy.**

INDICATIONS AND USAGE

Vitafol ®-OB+DHA is indicated to provide vitamin, mineral and omega-3 fatty acid supplementation prior to conception, throughout pregnancy, and during the postnatal period for the lactating and non-lactating mother.*

Vitafol ®-OB+DHA does not contain fish, fish oils, fish proteins or fish byproducts.

CONTRAINDICATIONS

Vitafol ®-OB+DHA is contraindicated in patients with hypersensitivity to any of its components or color additives.

Folic acid is contraindicated in patients with untreated and uncomplicated pernicious anemia, and in those with anaphylactic sensitivity to folic acid.

Iron therapy is contraindicated in patients with hemochromatosis and patients with iron storage disease or the potential for iron storage disease due to chronic hemolytic anemia (e.g., inherited anomalies of hemoglobin structure or synthesis and/or red cell enzyme deficiencies, etc.), pyridoxine responsive anemia, or cirrhosis of the liver.

Cyanocobalamin is contraindicated in patients with sensitivity to cobalt or to cyanocobalamin (vitamin B-12).

Warning

Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6. Keep this product out of reach of children. In case of accidental overdose, call a doctor or a Poison Control Center immediately.

WARNINGS/PRECAUTIONS

Vitamin D supplementation should be used with caution in those with hypercalcemia or conditions that may lead to hypercalcemia such as hyperparathryroidism and those who form calcium-containing kidney stones. High doses of vitamin D can lead to elevated levels of calcium that reside in the blood and soft tissues. Bone pain, high blood pressure, formation of kidney stones, renal failure, and increased risk of heart disease can occur.

Prolonged use of iron salts may produce iron storage disease.

Folic acid, especially in doses above 0.1 mg daily, may obscure pernicious anemia, in that hematologic remission may occur while neurological manifestations remain progressive.

The use of folic acid doses above 1 mg daily may precipitate or exacerbate the neurological damage of vitamin B12 deficiency. Consumption of more than 3 grams of omega-3 fatty acids per day from all sources may lead to excessive bleeding.

Supplemental intake of omega-3 fatty acids, such as DHA exceeding 2 grams per day is not recommended.

Avoid overdosage. Keep out of the reach of children.

Drug Interactions

High doses of folic acid may result in decreased serum levels of the anticonvulsant drugs.

Vitamin D supplementation should not be given with large amounts of calcium in those with hypercalcemia or conditions that may lead to hypercalcemia such as hyperparathyroidism and those who form calcium-containing kidney stones.

Zinc can inhibit the absorption of certain antibiotics; take at least 2 hours apart to minimize interactions.

Consult appropriate references for additional specific vitamin-drug interactions.

Information for Patients

Patients should be counseled to disclose all medical conditions, including use of all medications, vitamins and supplements, pregnancy, and breast-feeding.

Pediatric Use

Not for pediatric use.

ADVERSE REACTIONS

Adverse reactions have been reported with specific vitamins and minerals, but generally at doses substantially higher than those in Vitafol ®-OB+DHA. Allergic reactions have been reported with some forms of gum acacia to include respiratory problems and skin lesions.

Contact your doctor for medical advice about serious adverse events. To report a serious adverse event or obtain
product information, contact 1-877-324-9349.

DOSAGE AND ADMINISTRATION

Before, during and after pregnancy, take one caplet and one soft-gel capsule by mouth daily, or as directed by a physician.

HOW SUPPLIED

Vitafol ®-OB+DHA is available as a light blue caplet debossed EV0079 and one amber-colored DHA softgel capsule. Available in Box of Unit-Dose pack of 30 (5 child resistant blister cards of 6 caplets and 6 softgel capsules each) (0642-0076-30) and as professional samples (0642-0076-03).

Store at room temperature, approximately 15°-30°C (59°-86°F), avoid excessive heat and moisture.

*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

Rx

Distributed by:
Exeltis USA, Inc.
Florham Park, NJ 07932

1-877-324-9349
www.exeltisusa.com

U.S. Patent No. 6,814,983; 7,390,509

Vitafol ® is a trademark of Exeltis USA, Inc.

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PRINCIPAL DISPLAY PANEL - Kit Carton

0642-0076-30

Vitafol ®-OB+DHA

Prenatal Supplement with DHA

SUGAR, LACTOSE, GLUTEN AND IODINE FREE

New

Smaller DHA Softgel

DOES NOT CONTAIN

FISH OIL

R X

Unit Dose Pack

30 Caplets and 30 Softgel Capsules

U.S. Patented

VITAFOL-OB PLUS DHA PRENATAL SUPPLEMENT PLUS DHA

vitamin a, ascorbic acid, vitamin d, .alpha.-tocopherol, thiamine mononitrate, riboflavin, niacin, pyridoxine hydrochloride, folic acid, cyanocobalamin, calcium, iron, magnesium, zinc, copper, and doconexent kit

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0642-0076

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0642-0076-30	1 in 1 CARTON	02/16/2007	

2	NDC:0642-0076-03	1 in 1 CARTON	02/16/2007	

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	0 BOX	1
Part 2	1 BOX	30

Part 1 of 2

VITAFOL-OB

vitamin a, ascorbic acid, vitamin d, .alpha.-tocopherol, thiamine mononitrate, riboflavin, niacin, pyridoxine hydrochloride, folic acid, cyanocobalamin, calcium, iron, magnesium, zinc, and copper tablet, coated

Product Information	
Route of Administration	ORAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	70 mg
VITAMIN D (UNII: 9VU1KI44GP) (CHOLECALCIFEROL - UNII:1C6V77QF41)	VITAMIN D	10 ug
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1) (.ALPHA.-TOCOPHEROL - UNII:H4N855PNZ1)	.ALPHA.-TOCOPHEROL	13.5 mg
THIAMINE MONONITRATE (UNII: 8K0I04919X) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE	1.6 mg
RIBOFLAVIN (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	1.8 mg
NIACIN (UNII: 2679MF687A) (NIACIN - UNII:2679MF687A)	NIACIN	18 mg
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE HYDROCHLORIDE	2.5 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1700 ug
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	12 ug
CALCIUM (UNII: SY7Q814VUP) (CALCIUM - UNII:SY7Q814VUP)	CALCIUM	100 mg
IRON (UNII: E1UOL152H7) (IRON - UNII:E1UOL152H7)	IRON	65 mg
MAGNESIUM (UNII: I38ZP9992A) (MAGNESIUM - UNII:I38ZP9992A)	MAGNESIUM	25 mg
ZINC (UNII: J41CSQ7QDS) (ZINC - UNII:J41CSQ7QDS)	ZINC	25 mg
COPPER (UNII: 789U1901C5) (COPPER - UNII:789U1901C5)	COPPER	2 mg
VITAMIN A (UNII: 81G40H8B0T) (VITAMIN A - UNII:81G40H8B0T)	VITAMIN A	810 ug

Inactive Ingredients	
Ingredient Name	**Strength**
HYDROXYPROPYL METHYLCELLULOSE (UNII: 3NXW29V3WO)	
COPOVIDONE K25-31 (UNII: D9C330MD8B)	
MANNITOL (UNII: 3OWL53L36A)	

POLYDEXTROSE (UNII: VH2XOU12IE)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
SOYBEAN (UNII: L7HT8F1ZOD)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MODIFIED CORN STARCH (1-OCTENYL SUCCINIC ANHYDRIDE) (UNII: 461P5CJN6T)	
STARCH, CORN (UNII: O8232NY3SJ)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
ACACIA (UNII: 5C5403N26O)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
TRIACETIN (UNII: XHX3C3X673)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics

Color	blue	**Score**	no score
Shape	OVAL	**Size**	19mm
Flavor		**Imprint Code**	EV0079
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		30 in 1 BOX; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		02/16/2007	

Part 2 of 2

DHA

doconexent capsule

Product Information

Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DOCONEXENT (UNII: ZAD9OKH9JC) (DOCONEXENT - UNII:ZAD9OKH9JC)	DOCONEXENT	250 mg

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	yellow (Amber)	**Score**	no score
Shape	OVAL	**Size**	15mm
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		30 in 1 BOX; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
DIETARY SUPPLEMENT		02/16/2007	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		02/16/2007	

Labeler - Exeltis USA, Inc (071170534)

Registrant - Exeltis USA, Inc (071170534)